

JUN 23 2000

K001277

510(k) Summary

Name of Sponsor: **DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact: **Marcia J. Arentz**
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4940

Trade Name: **TriFlange™ Acetabular Cup System**

Common Name: Patient specific flanged acetabular cup system

Classification: Class II

Device Product Code: Code: **87LPH** Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous uncemented
Code: **87 MEH** Prosthesis, Hip Semi-Constrained, Uncemented, Metal/Polymer, Non-porous, Calcium-phosphate

Substantially Equivalent Device: DePuy Duraloc® 400 Acetabular Cup..... K952740
DePuy Protrusio Cage..... K962007
Biomet Patient Matched Flanged
 Acetabular Component K983035
Sulzer Inter-Op™ HA Porous
 Acetabular System K972393
Zimmer Harris/Galante Porous K980711
 Hip Prosthesis With HA/TCP Coating

Device Description: The patient specific TriFlange™ Acetabular Cup System is an acetabular cup system designed and manufactured to match the individual patient's anatomy. The system consists of a porous coated Duraloc acetabular cup with three patient specific illial, ischial and pubic flanges added to reinforce weak acetabula similar to the Protrusio Cage. The device may be fixed in place with titanium bone screws of various lengths through a variety of screw holes in the flanges.

Intended use: The TriFlange™ Acetabular Cup System is intended to be used with the Duraloc® UHMWPE liners to resurface the acetabular socket in cementless application during total hip arthroplasty.

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Indications for use:

The TriFlange™ Acetabular Cup System is indicated for use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged by disease, deformity, or trauma including non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis and diastrophic variant.

Substantial equivalence:

The TriFlange™ Acetabular Cup System with patient specific flanges is substantially equivalent to the currently marketed DePuy Duraloc® Acetabular Cup (K952740), the DePuy Protrusio Cage (K962007) the Biomet Patient Matched Flanged Acetabular Component (K983035), the Sulzer Inter-Op™ HA Porous Acetabular System (K972393) and the Zimmer Harris/Galante Porous Hip Prosthesis With HA/TCP coating (K980711).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K001277

Trade Name: TriFlange™ Acetabular Cup System
Regulatory Class: II
Product Code: LPH, MEH
Dated: April 20, 2000
Received: April 21, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Dawn R. Vachner -
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001277

Device Name: TriFlange™ Acetabular Cup System

Indications for Use:

The TriFlange™ Acetabular Cup System is intended to be used with the Duraloc® polyethylene liners to resurface the acetabular socket in cementless application during total hip arthroplasty. The device is indicated for use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged by disease, deformity, or trauma including non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis and diastrophic variant.

Concurrence of CDRH, Office of Device Evaluation

Diane P. Lochner
(Division Sign-Off)
Division of General Restorative Devices

Prescription Use X OR

Over-The-Counter Use 510(k) Number K001277

(Per 21 CFR 801.109)

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